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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,857	11/20/2001	Roberto Macina	DEX-0273	1527

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EXAMINER
WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/001,857	MACINA ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5, 6-9,14,15 and 18-23* is/are pending in the application.

4a) Of the above claim(s) *6 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-9, 15 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. Applicant's amendment filed on June 8, 2004 is acknowledged and has been entered. Claims 1, 14 and 15 have been amended. Claims 10-13 and 16-17 have been canceled. Claims 18-23 have been added. Claims 1-5, 6-9, 14, 15 and 18-23 are pending. Claims 6 and 14 are withdrawn from consideration as being drawn to a non-elected invention.

3. Claims 1-5, 7-9, 15 and 18-23 are discussed in this Office action.

4. All of the amendments and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on July 19, 2004 is acknowledged. A signed copy of the form-1449 is being submitted with this Final Action.

Previous Rejections

6. The objections to the specification are withdrawn in view of Applicant's amendment to the specification. The claim rejection under 35 USC 101 and 35 USC 112 first paragraph directed to claims 1-5, 7-9 and 15 as lacking utility and enablement is

maintained and discussed below. The claim rejection under 35 USC 112 first paragraph directed to claims 1-5, 7-9 and 15 as lacking adequate written description is maintained and discussed below. The claim rejection under 35 USC 112 second paragraph directed to claims 1-5 being vague and indefinite is withdrawn in view of Applicant amendment to claim 1. The claim rejection under 35 USC 112 second paragraph directed to claim 15 as being vague and indefinite is withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 101

7. Once again, the claims 1-5, 7-9 and 15 are rejected under 35 USC 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for the nucleic acid sequence mentioned in the claims. The instant application does not disclose a connection between presence or expression of SEQ ID NO: 42 and lung cancer. For example, none of the tables between pages 117-118 and 121-127 show such nexus. The demonstration of expression of a sequence in a specific tissue type cannot be translated to mean that that sequence is necessarily a marker for cancer in that tissue. In addition, the application does not disclose or teach the meaning or significance of any particular assay for expression of SEQ ID NO: 42. Thus, the instant application does not disclose a specific, substantial, and credible utility for SEQ ID NO: 42, nor is there a readily apparent utility under 35 USC 101 for SEQ ID NO: 42.

Claim Rejections - 35 USC § 112 first paragraph

8. Once again, claims 1-5, 7-9 and 15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible or an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make and/or use the claimed invention. The discussion in the rejection under 35 USC 101 is incorporated here.

Applicant's Traversal

9. Applicant traverses the rejections on the following ground: Applicant summarizes the Examiner's rejection and states that the instant applicant claims the benefit of priority from US provisional application serial number 60/252,054, filed November 20, 2000, the entire content of which were incorporated by reference in their entirety into the instant application (recited on page 1, lines 4-6 of the instant application). Applicant states that in the priority application, parent sequence SEQ ID NO: 41, referred to therein as SEQ ID NO: 33, was demonstrated by suppression subtractive hybridization to be a lung cancer specific marker. Applicant states that these experiments described at pages 26 through 20 of the provisional application, which demonstrates utility of the instant claimed invention, have been incorporated at page 118, line 16. Applicant states that no new matter is added by this amendment. Applicant further asserts that case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and this satisfies the

utility requirement (*Nelson v. Bowler, 626 F.2.d 858, 206 USPQ 881, 883 (CCPA)*). Applicant states that clearly identification of SEQ ID NO: 33, a related sequence to SEQ ID NO: 41 and 42 as being a lung cancer specific marker constitutes a pharmacological activity relevant to the asserted use as a diagnostic for lung cancer, thus satisfying the utility requirement. Applicant has canceled claim 17 thus mooting rejections relating to this claim.

Examiner's Response

8. All of the arguments filed on June 8, 2004 have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: In response to Applicant's arguments that the amendment to the specification by incorporating the entire content of the provisional application 60/252,054 establishes utility for the instant invention, the Examiner respectfully disagree. The amendment to the specification incorporating the content from the provisional application recited above teaches that "several subtracted libraries were generated for lung tissue". Applicant states that "the product of the subtraction experiments was used to generate cDNA libraries and these cDNA libraries contain expressed sequence tags from genes that are lung specific, or upregulated in lung tissue". Applicant states that "randomized clones from each cDNA PCR select library were sequenced and the genes identified by a systematic analysis of the sequence data against the LIFESEQ Gold database" using the CLASP software (page Example 1 and 1a). While the Examiner acknowledges Applicant's amendment and arguments and Applicant's citation of case law on utility, Applicant has not shown either that the nucleic acid molecules comprising SEQ ID NOS: 41 and 42 are expressed only in

lung cancer tissue or that it has any "pharmacological activity". The only fact Applicant has assert is that the sequences of the instant invention, including SEQ ID NOS: 41 and 42, seem to be expressed in lung tissues based on the results of a computerized database search of a single database. No further explanation has been provided in the specification regarding SEQ ID NO: 41 or 42 except that the sequences are located on chromosome 9 (page 117). It is not clear the source of the nucleic acid (cell culture or tumor) and/or the levels of expression of SEQ ID NO: 41 or 42 in cancer cells versus normal cells. Such data is totally inconclusive, as other databases or results published elsewhere may show that SEQ ID NO: 41 and/or 42 is expressed in normal lung tissues as well. Further, even if one were to rely on that single database, the question of the comparative levels of expression of SEQ ID NO: 41 and/or 42 in cancerous versus normal tissues, *critical* to the utility of SEQ ID NOS: 41 and 42 as being indicative of tumorogenesis, remains unanswered. In order for SEQ ID NOS: 41 and 42 to be diagnostic for lung cancer, its level of expression in lung cancer cells would have to be significantly higher than in normal lung cells as well as in other tissues and organs of the body. Applicant provides no conclusive evidence that this is indeed the case. Therefore, Applicant has not provided a nexus between the presence of or expression of SEQ ID NOS: 41 and 42 a use of the sequences as markers for the diagnosis or detection of lung cancer. The presence of a polynucleotide in lung tissue cells is not sufficient for establishing a utility in a diagnosis of a disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed nucleic acid and the disease. If a molecule is to be used as a surrogate for a disease state, some disease must be identified in some way with the molecule. There must be some expression pattern that would

allow the claimed polypeptide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in significantly higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing" *Brenner,* 148 USPQ at 696. The instant disclosure does not present a substantial utility that would support the requirements of 35 USC 101. It appears, at best, that Applicant has shown a relation to an association with lung tissue. This utility is not specific because there are a lot of different nucleic acids expressed in lung tissue, 115 of them provided by Applicant. Thus the presence of the nucleic acids in lung tissue does not provide a specific utility because there is no direct or even indirect connection made between any particular utility and the nucleic acids comprising SEQ ID NO 41 and 42. Accordingly, the rejection under 35 USC 101 is maintained.

It is noted that the rejections under 35 USC 112 first paragraph, as failing to comply with the enablement requirement, is repeated above for reasons already made of record (e.g., Office action mailed on January 8, 2004, page 7). The Examiner's

discussion in the rejection under 35 USC 101 hereinabove is incorporated here. Accordingly, the rejection under 35 USC 112 first paragraph is maintained.

Claim Rejections - 35 USC § 112: Lack of adequate written description

9. Once again, claims 1-5, 7-9 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It is noted that applicant's amendment of the claims to encompass stringent hybridization conditions and a limitation of at least 90% sequence identity is acknowledge and discussed here for claims 1-5, 7-9 and 15. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-5, 7-9 and 15 are drawn to an isolated nucleic acid molecule comprising (a) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO:145; (b) a nucleic acid molecule comprising a nucleic acid sequence selected from SEQ ID NO: 41 or 42; (c) a nucleic acid molecule that hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b); or (d) a nucleic acid molecule having at least 90% sequence identity to the nucleic acid molecule of (a) or (b). The claims are also drawn to vector, host cells, and kit comprising said nucleic acids. The claims encompass a large genus of nucleic acid species not adequately described or disclosed. Specifically, the specification nor examples beginning at page 116 describe or disclose the numerous nucleic acid molecules which hybridizes to or is capable of hybridizing with the

sequences of SEQ ID NO: 41 and/or 42. Likewise, the specification does not describe or disclose any functionality of the undisclosed nucleic acid molecules associates with a sequence having only at least 90% identity to SEQ ID NO: 41 or SEQ ID NO: 42. Thus, the scope of the claims includes numerous structural variants thereof, and the genus is highly variable because a significant number of structural differences between genus members are permitted. Likewise the specification or claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 41 and/or SEQ ID NO: 42 alone is insufficient to describe the genus. A representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus applicant was not in possession of the claimed genus.

Applicant's Traversal

10. Applicant traverses the rejection on the following grounds: Applicant summarizes the Examiner's rejection as asserts that the Examiner's suggestion that structural features

that could distinguish compounds in the genus from other are missing from the disclosure and that no common structural attributes identify the members of the genus. Applicant states that all claimed nucleic acid sequences are distinguished based upon their common structural similarities to reference sequences explicitly disclosed in the instant specification. Applicant asserts that further, in an earnest effort to clarify structural limitations of the claimed nucleic acid sequences, claim 1, part (c) has been amended to set froth specific conditions of stringent hybridization as set forth in pages 14-16 used to identify the claimed sequences. Applicant states that claim 1(d) has also been amended in accordance with teachings at page 32-33 to state that the nucleic acid sequences has 90% sequence identity to a nucleic acid sequence encoding SEQ ID NO: 145 or a nucleic acid comprising SEQ ID NO: 41 or 42. Applicant contends that contrary to the Examiner's arguments, detailed methodologies for ascertaining sequences which meet the structural limitations of the instant amended claims are set forth in the specification at page 13, through page 16 and page 32 through 33. Applicant states that further methods for assessing percent sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Applicant states that this, upon discovery of the instant claimed nucleic acid sequences of SEQ ID NO: 41 and 42 and their specificity in lung tumor tissues, applicant were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence as well as the amino acid sequence encoded thereby. Finally Applicant concludes that the instant specification and its teachings clearly place the public in possession of theses sequences as well.

Examiner's Response

11. All of the amendment and arguments filed on June 8, 2004 have been thoroughly reviewed and considered but are not found persuasive for the following reasons: In response to Applicant's arguments that the amendment to claim 1, introducing a limitation of stringent hybridization conditions to part c) and a limitation of at least 90% sequence identity in part d) overcomes the rejection under 35 USC 112 first paragraph, the Examiner respectfully disagree because Applicant does not describe any nucleic acids which hybridize to SEQ ID NOS: 41 or 42 under stringent hybridization conditions. Nor is there a description of any nucleic acids which have at least 90% sequence identity to SEQ ID NOS: 41 and 42. Although the specification only discloses the sequence of SEQ ID NO: 41 or 42, these embodiments disclosed herein encompass **a large genus of related nucleic acids which are not describe or disclosed anywhere in the specification and were not in Applicant's possession**. Included in this genus are any number of nucleic acids which have some sequence homology with SEQ ID NOS: 41 or 42, but nonetheless have substantially different and unpredictable properties, such as encoding a polypeptide of substantially or completely different biological function. Thus, the specification does not have adequate written descriptive support for the large genus as set forth in the claims as amended. Accordingly, the rejections under 35 USC 112 first paragraph are maintained.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

New Matter

12. The amendment filed June 8, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The added material which is not supported by the original disclosure is at follows: "α- mating system" (page 48, line 24 and page 75, line 16).

Claim Rejections - 35 USC § 101 Utility and 35 USC § 112 enablement

13. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Newly added claims 18-23 are rejected under 35 USC 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for the nucleic acid sequence mentioned in the claims. The instant application does not disclose a connection between the presence of or expression of SEQ ID NO: 41 or 42 and lung cancer. For example, none of the tables between pages 117 through 140 shows such nexus. In the specification, nucleic acid molecules with SEQ ID NO: 41 or 42 were identified by data mining of sequences in the Incyte genomics LIFESEQ database using the CLASP software (page 116). No further explanation has been provided in the specification regarding SEQ ID NO: 41 or 42, except that they are located on Chromosome 9 (page 117). It is not clear the source of the nucleic acid (cell culture or tumor) and/or the level of expression of SEQ ID NO: 41

or 42 in cancer cells versus normal cells. Therefore, no connection between the presence of or expression of SEQ ID NO: 41 or 42 and lung cancer is evident because it is not clear how a nucleic acid molecule comprising SEQ ID NO: 41 or SEQ ID NO: 42 or the encoded polypeptide of SEQ ID NO: 145 could be used for detection of lung malignancies. In the instant application, additional research would be necessary to establish substantial utility of a nucleic acid molecule comprising SEQ ID NO: 41 or 42 or the encoded protein based on the lack of information in the specification. In order for a polynucleotide to be useful for diagnosis of a disease, there must be a *well-established* or *disclosed* correlation or relation between the claimed polynucleotide and a disease or disorder. The presence of a polynucleotide in lung tissue cells is not sufficient for establishing a utility in a diagnosis of a disease in the absence of some information regarding a correlative or causal relationship between the expression of claimed nucleic acid and the disease. If a molecule is to be used as a surrogate for a disease state, some disease must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polypeptide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in significantly higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disease and the lack of any correlation between the claimed polynucleotide or the

encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing" *Brenner,* 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirements of 35 USC 101. It appears, at best, that Applicant has shown a relation to an association with lung tissue. This utility is not specific because there are a lot of different nucleic acids expressed in lung tissue, 115 of them provided by Applicant. Thus the presence of the nucleic acids in lung tissue does not provide a specific utility because there is no direct or even indirect connection made between any particular utility and the nucleic acid comprising SEQ ID NO: 41 and 42 or the encoded protein of SEQ ID NO: 145. In view of the foregoing, the instant application does not disclose a specific or substantial, or readily apparent utility under 35 USC 101 for instant invention.

15. Claims 18-23 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible or an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make and/or use the claimed invention.

The discussion in the rejection under 35 USC 101 is incorporated here.

Claim Rejections - 35 USC § 112: Written Description

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitations wherein the nucleic acid molecules of claim 1 have at least 95% or at least 98% or at least 99% sequence identity to the nucleic acid molecule of (a) or (b) lacks adequate written description because these embodiments cover a large genus of related nucleic acids which are not described and were not in Applicant's possession. Included in this genus are any number of nucleic acids which have some sequence homology with SEQ ID NO: 41 or 42, but nonetheless have substantial different and unpredictable properties, such as encoding a polynucleotide of substantially or completely different biological function. The sequence of SEQ ID NO: 41 or SEQ ID NO: 42 alone is insufficient to describe the genus. A representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus applicant was not in possession of the claimed genus.

Conclusion

18. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE**

FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

CYNTHIA WILDER
PATENT EXAMINER